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(54) Shape memory locking mechanism for intravascular stents

(57) An expandable intraluminal vascular graft is implanted in a coronary artery or other vessel to maintain the patency of the lumen. The vascular graft, commonly referred to as a stent, expands from a first diameter to a second diameter, and a plurality of teeth are moved in relation to a longitudinal slot to lock the stent in an expanded condition.

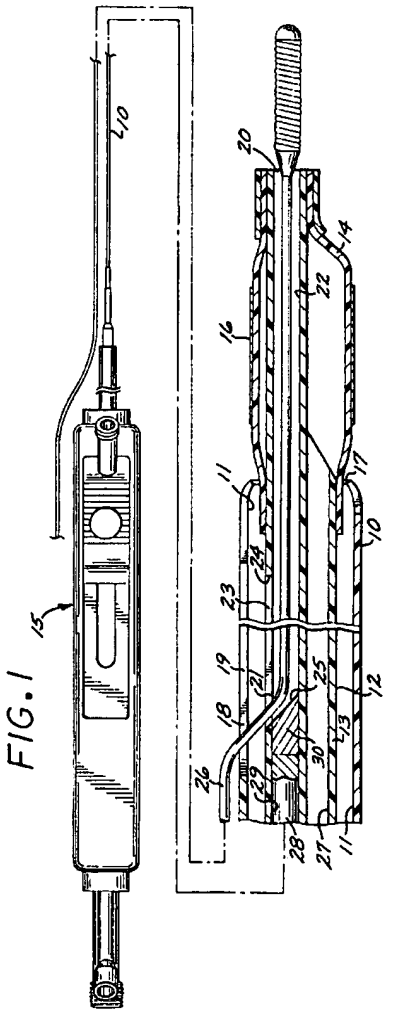

FIG. 1

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention generally relates to expandable endoprosthesis devices, in particular expandable intraluminal vascular grafts, generally referred to as stents, that are adapted to be implanted in a body lumen, such as a coronary artery or other vessel to maintain the patency of the lumen. These devices frequently are used in the treatment of atherosclerotic stenosis in blood vessels especially after percutanecus transluminal coronary angioplasty (PTCA) procedures, with the intent of reducing the likelihood of restenosis of a blood vessel. Stents also are used to support a body lumen where a flap or dissection has occurred or, in general, whenever a lumen is weak. The present invention also relates to an expandable intraluminal vascular graft that can be used in essentially any body lumen.

DESCRIPTION OF RELATED ART

In expandable stents that are delivered with expandable catheters, such as balloon catheters, the stents are positioned over the balloon portion of the catheter and are expanded, from a reduced diameter to an enlarged diameter greater than or equal to the diameter of the arterial wall, by inflating the balloon. Stents of this type can be expanded to an enlarged diameter by deforming the stent, by engagement of the stent walls with respect to one another, and by one-way engagement of the stent walls together with endothelial growth onto and over the stent. Other stents are self-expanding, through the properties of the material constituting the stent or by design. Examples of intravascular stents can be found in U.S. Patent No. 5,292,331 (Boneau); U.S. Patent No. 4,776,337 (Palmaz); U.S. Patent No. 4,580,568 (Gianturco); U.S. Patent No. 4,856,516 (Hillstead); and U.S. Patent No. 5,092,877 (Pinchuk).

Current stent designs include a series of stents which are interconnected and which utilize teeth on their outer edges to ratchet through a slot in order to achieve mechanical locking of a stent in a cylindrical form. Examples of such ratcheting stents can be found in copending application U.S. Serial No. 08/052,410 and assigned to common assignee, Advanced Cardiovascular Systems, Inc. The ratcheting stent design of the prior art is generally made of 316L stainless steel, poly-L-lactic acid (LPLA), poly-DL-lactic acid (DLPLA), or polycaprolactone (PCL) polymers. If one is not careful, during the manufacturing process of rolling, and during the deployment process in implanting the stent; it is possible that the teeth, because of the polymer material properties, may be deformed or damaged and thus may affect stent-locking integrity. Further, the ratcheting forces required to expand and deploy the stent can be higher than would be ideal because of the interference between the teeth and the locking slot. Also, the interference of the teeth with the locking slot might be somewhat offset and might cause an uneven expansion of the individual rings of the stent.

Because the present stent is made from a shape-memory material, the interlocking teeth do not engage the slot until after expansion has occurred, and thus some of the difficulties with the prior art devices are eliminated.

SUMMARY OF THE INVENTION

Preferred embodiments of the invention are directed to an intravascular stent which is adapted to be inserted within a body lumen and which is designed to expand and lock therein in an enlarged diameter form. The stent is designed to engage into the locked position after the stent has been expanded, by utilizing shape-memory-retaining material in teeth which move, when heated, into engagement with a longitudinal slot. Thus, an intraluminal stent is formed from a substantially rectangular sheet having a longitudinal slot formed in one edge. A plurality of teeth are positioned along the edges of the sheet and the edges intersect with said longitudinal slot in a belt buckle fashion. The stent is rolled onto a balloon portion of a catheter to form a cylindrical configuration and the stent is delivered within a body lumen for deployment. The balloon portion of the catheter is expanded, which thereby expands the stent into engagement with the vascular wall of the body lumen. Thereafter, heat is applied to the stent and the teeth will move as a result of application of the heat so that the teeth will engage and interlock with the longitudinal slot. The stent then is locked in an open position to maintain the patency of the body lumen in which it is deployed. The teeth can be made from any shape-memory-retaining material such as nitinol a nickel-titanium alloy (NiTi). Generally NiTi, as used in this invention, is in the form of foil having either shape-memory effect (SME) or super-elasticity (SE).

Heat can be applied to the stent by several methods, one of which methods involves a heated balloon. A saline solution that is heated is used to inflate the balloon and to cause the temperature at the teeth to rise and to move into locking engagement with the longitudinal slot, as described above. Another method of heating the stent involves injecting heated saline into the body lumen after balloon expansion at the site of the implanted stent.

Preferred embodiments of the invention allow the stent to be expanded from a smaller diameter, as it is rolled on the balloon, to the larger expanded diameter, for implanting in the diseased area, without fear that the engaging teeth will be damaged or might cause the stent to deploy unevenly if one set of teeth engage while the other set does not. Further, deployment can be accomplished in a smoother and slower manner than with pre-

vious designs because the teeth are not ratcheting along the longitudinal slot as the stent is being expanded. It is only after the stent is expanded and heated that the teeth engage the longitudinal slot.

The stent may also be encapsulated by a polymer coating such that at least the locking mechanism components are protected by the coating. Thus, at least the teeth and the slot they engage are coated with a polymer. As is clear, however, other portions of the stent can be coated as well.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 depicts an intraluminal catheter having rapid exchange features for the purpose of delivering an intraluminal stent such as the stents shown in FIGS. 1 or 4.

FIG. 2 is an over-the-wire type intravascular catheter for delivering an intraluminal stent such as the stents depicted in FIGS. 1 or 4.

FIG. 3 is a top view of an intraluminal stent having a plurality of teeth which constitute locking mechanisms when in the closed position.

FIG. 4 is the intravascular stent of FIG. 3 wherein the plurality of teeth have moved outwardly into the locking position.

FIG. 4A is the intravascular stent of FIG. 4 wherein portions of the stent are encapsulated by a polymeric coating.

FIG. 5 is a perspective view of the intravascular stent of FIGS. 1 and 2 in which the stent has been rolled in a cylindrical configuration and the locking teeth have expanded into engagement with a slot.

FIG. 6 is a top view of a plurality of interconnected intravascular stents with the plurality of teeth on each of the stent ends in the closed position.

FIG. 7 depicts a top view of the intravascular stents of FIG. 4 wherein the plurality of teeth on each stent have opened outwardly for locking engagement.

FIG. 8 is a top view of an intraluminal stent wherein separate stent sections are mounted on the stent structure.

FIG. 9 is a top view of an intraluminal stent wherein separate stent sections each having a plurality of teeth in the closed position have been attached to the stent structure.

FIG. 10 is a cross-sectional view taken along lines 10-10 depicting the stent section attached to the stent body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

During PTCA procedures it is common to use a dilatation catheter to expand a diseased area to open the lumen of a patient so that blood can flow freely therethrough. Despite the beneficial aspects of PTCA procedures and its widespread and accepted use, it has several drawbacks, including restenosis and the risk of acute thrombosis and sub-acute closure. Recurrent stenosis has been estimated to occur in seventeen to fifty percent of patients despite the success of an initial PTCA procedure. Restenosis is a complex and not fully understood biological response to injury of a vessel which results in chronic hyperplasia of the neointima. This neointimal hyperplasia is activated by growth factors which are released in response to injury. Acute thrombosis also is a result of vascular injury and requires systemic antithrombotic drugs and possibly thrombolytics as well. Such therapy can increase bleeding complications at the catheter insertion site and may result in a longer stay in the hospital. Sub-acute closure can be a result of thrombosis, as can be elastic recoil and/or vessel dissection.

Several procedures have been developed to combat restenosis and sub-acute or abrupt closure, one of which is the delivery and implanting of an intravascular stent. Stents as yet are in a developmental stage, and are being used in clinical trials throughout the United States. The devices regularly are being implanted in patients in Europe and other countries. Generally stents can take numerous forms. The most common form, however, comprises a generally cylindrical hollow tube which holds open the vascular wall at the area that has been dilated by the dilatation catheter.

Typically, stents are mounted on the balloon portion of catheter while in a contracted state and then are delivered intraluminally to the injured or damaged area. The balloon is expanded and it in turn expands the stent into engagement with the vascular wall. The exact manner in which a particular stent maintains the patency of a lumen is a function of the particular design of the stent. There is a wide range of catheter systems available to deploy these stents, two of which are depicted in FIGS. 1 and 2. In FIG. 1 a rapid exchange catheter system is depicted and in FIG. 2 an over-the-wire system is depicted. Each system incorporates a retractable sheath which protects the stent and the vessel wall as the stent is transported through the vascular system of a patient. For purposes of the present invention, however, either system suffices and numerous other catheter systems would be appropriate, including perfusion catheters and dilatation catheters. Thus, FIGS. 1 and 2 illustrate a stent delivery system which embodies features of the invention.

Referring to FIG. 1, the delivery system includes a delivery sheath 10 which has an outer lumen 11 and an intravascular catheter 12 disposed within the outer lumen 11. The intravascular catheter has an elongated catheter body 13 and a balloon 14 on the distal portion of the catheter body. A manipulating device 15 is provided on the distal end of the delivery system, which is employed to affect relative axial or longitudinal movement between the delivery sheath 10 and the intravascular catheter 12. An intravascular stent 16, which is to be delivered and implanted within a body lumen of a pa-

tient, is mounted on the exterior of the balloon 14.

The delivery sheath 10 has a distal port 17 in its distal end, which is in fluid communication with the outer lumen 11 and a proximal port 18 disposed proximally to the distal port. The distal portion of the delivery sheath 10 tapers down in a spherical-like manner so that the cross-sectional area is somewhat less in the distal region than it is in the other portions of the delivery sheath. A slit 19 extends from the proximal port 18 to a location just proximal to the distal port 17.

The intravascular catheter 12 has a distal port 20 and a proximal port 21 which are in fluid communication with a first inner lumen 22 extending within the distal portion of the catheter 12. This first inner lumen 22 is adapted to slidably receive a guidewire therein. A slit 23 extends from the proximal port 21 to a location 24 proximal to the proximal end of balloon 14. The proximal end of the guidewire receiving first inner lumen 22 is provided with a ramp 25 to guide the proximal end of guidewire 26 out of the proximal port 21 of intravascular catheter 12 when the catheter is mounted onto the guidewire, as will be discussed hereinafter. A second, much longer, inner lumen 27 is provided within the catheter body 13, to direct inflation fluid from the proximal end of the catheter body to the interior of balloon 14.

Proximal to the proximal port 21 in the catheter body 13 is a stiffening member 28 which is disposed in a third inner lumen 29 provided within the catheter body 13. As shown in the drawings, the third inner lumen 29 and the first inner lumen 22 may be the same lumen with a plug 30 separating the two lumens. The ramp 25 is on the distal side of plug 30.

In a typical stent deployment, the intravascular stent 16 will be implanted in the vascular system of a patient at the site of the diseased or injured area to provide sufficient blood flow through the vessel. The implanted stent 16 will aid in the prevention of restenosis, abrupt closure, and poor angiographic results. Typically, in these situations the distal end of a guidewire 26 (or other guiding member) extends across the damaged section of the artery, while the proximal and of the guidewire 26 extends out of the patient during the entire procedure and is inserted through the distal port 20 in the distal end of the catheter 12 and advanced proximally through the first inner lumen 22 until the proximal end of the guidewire impacts the ramp 25 and is thereby directed through the proximal port 21.

The intravascular catheter 12 preferably is positioned within the outer lumen 11 of the delivery sheath 10 so that at least a significant portion of the proximal port 18 in the sheath is in alignment with the proximal port 21 of the intravascular catheter. In this manner, proximal advancement of the guidewire 26 through the inner lumen 22 also will direct the proximal end of the guidewire out of the proximal port 18 in the delivery sheath. The proximal end of the guidewire 26 then manually may be held to maintain the position of the guidewire across the targeted area of deployment, while the catheter 12 and the stent 16 are advanced over the guidewire and through the vascular system of the patient. The advancement of the catheter system with the stent 16 mounted thereon continues until the distal ends of the catheter and sheath extend adjacent to, or across, the area targeted for deployment. Next, the manipulator 15 on the proximal end of the delivery system is actuated to move the sheath 10 proximally with respect to the catheter 12 and to thereby expose the stent 16 which is mounted on the balloon 14. Thereafter, inflation fluid is directed under substantial pressure through the inflation lumen 27 in the catheter body 13 to the interior of the balloon 14, thereby expanding the balloon and simultaneously expanding the stent 16 against the vessel wall of the patient. After the balloon 14 is deflated, the delivery systems, both the sheath 10 and the catheter 12, then are removed from the patient, along with the guidewire 26, leaving the expanded stent 16 pressed against the vessel wall.

In another embodiment of the invention, as is depicted in FIG. 2, an over-the-wire catheter system is employed to deliver the stent 16 within the vasculature of the patient to the damaged area. A guidewire 26 is employed to cross a damaged area and to locate the position within the patient so that the intravascular catheter 12 can reach the diseased or damaged area. As is typical in over-the-wire catheter systems, the intravascular catheter has an outer member 37 and an inner member 38 which are coaxially aligned. The inner member 38 has an inner lumen 39 which carries a guidewire 26. The guidewire can move freely within inner lumen 39 in an axial direction. The intravascular catheter is slidably disposed within the sheath 10 in the inner lumen 11. A port 17 at the distal end of sheath 10 provides an opening through which the catheter can extend.

The method of deploying the stent 16 is similar to that described for the rapid exchange system above and as depicted in FIG. 2. Generally, the guidewire 26 is positioned at a location just past the targeted site of deployment and the catheter system is threaded over the guidewire 26 so that the balloon 14, along with the stent 16 is positioned at the targeted area. Thereafter, the balloon 14 is expanded radially outwardly to thereby expand and deploy the stent 16 by forcibly expanding it into the vessel wall. The balloon 14 then is deflated and the catheter system 12 is withdrawn from the vasculature of the patient leaving the stent 16 securely implanted in the damaged or injured area.

Consistent with the embodiment depicted in FIGS. 3 and 4, the intravascular stent 16 is depicted as a flat sheet which can be manufactured in numerous ways, including by use of laser or chemical etchants. For example, a pattern is cut from a sheet of metal by using a CO_2 laser or a Nd:YAG (neodymium:yttrium aluminum-garnet) laser to cut the pattern. Alternatively, a known etching process can be used to remove metal, leaving the pattern depicted in FIGS. 3 or 4. Both laser and chemical etchant processes are described in U.S. Serial

No. 08/164,986, commonly assigned to Advanced Cardiovascular Systems, Inc. Other known methods of making the stent 16 include stamping and using a process of EDM (electronic discharge machining).

The stent 16 depicted in FIG. 3 has a first edge 40 and a second edge 42, a third edge 44 and a fourth edge 46. It is desirable to have open spaces 49 cut within the stent body to allow more flexibility and to permit endothelial cell growth through the openings after the stent has been implanted and to allow for side branch flow and vessel wall oxygenation. The open spaces 49 can take any geometric shape as long as the expanded radial strength of the stent 16 is maintained. A plurality of the teeth 50 are formed along the third edge 44 and fourth edge 46 and appear in a closed position. The teeth 50 are desirably made from a shape-memory or super-elastic material such as nitinol (NiTi) (see FIG. 8). The remainder of the stent 16 can be made of known materials such as stainless steel, tantalum, polymers, or composites of these materials. Further, the closed teeth 50 can be attached to the third edge 44 and the fourth edge 46 by known means such as welding, brazing, staking, adhesives, or chemical bonding (see FIG. 8). It also is contemplated that all of the stent 16 can be made from a NiTi material, which would make the manufacturing process somewhat less complex.

In order to deploy the stent 16 in the vasculature of a patient, the stent must be capable of being rolled into a cylindrical configuration having a relatively low profile for delivery through the vascular system. Thereafter, and as is described above, the balloon portion of a catheter will expand the stent 16 to an enlarged diameter whereafter it will press against the vessel wall and will remain open. The present invention provides for a stent that is capable of expanding in a controlled manner and locking after the stent has been expanded.

As is depicted in FIG. 4A, portions of the stent of the present invention can be encapsulated by a polymeric material. For example, the stent 16 may have a polymeric coating 57 on open teeth 56A, a first edge 40A, a third edge 44A, a fourth edge 46A, and longitudinal slot 48A. Further, the polymeric coating 57 can fill the openings 58. A plurality of holes 59 are formed in the polymeric coating 57 to provide more flexibility for the stent 16 and to provide more uniform expansion. The polymeric coating 57 can be comprised of poly-L-lactic acid (LPLA), poly-DL-lactic acid (DLPLA) or polycaprolactone (PCL) polymers, and the polymers can be infused or otherwise characterized by a therapeutic drug which diffuses into the body lumen of the patient at a controlled (predetermined) rate.

Consistent with one embodiment and as depicted in FIG. 5, the stent 16 is rolled into a cylindrical configuration by inserting the first edge 40 through the longitudinal slot 48. The closed teeth 50 will not engage the edges 54 of the longitudinal slot 48, since the teeth 50 are in a closed position and will simply slide past the edges 54. In this manner, and as has been described above, the stent can be mounted on a balloon portion of a catheter and the teeth 50 will not engage with the edges 54 during either the rolling process or the expansion process as is described further.

During the delivery and implantation of the stent 16, the catheter is used to position the balloon and stent in the diseased or injured area. Thereafter, the balloon is expanded to expand the stent 16 radially outwardly and into contact with the vessel wall. As the closed teeth 50 move past the edges 54 and slide through the longitudinal slot 58, there is an even and uniform expansion of the stent because the teeth do not engage the edges. After fully expanding the stent, however, it is desirable to lock the stent in its fully-open position.

Thus, it is desirable to move the teeth 50 into an open position as shown by the open teeth 56 in FIGS. 4 and 5. The teeth 56 move into an open position when heated to a specific, predetermined temperature. For example, a heated saline solution or other fluid can be injected into the balloon, thereby heating the stent 16 and the teeth 56. Another method of heating includes injecting a heated saline solution into the body lumen at the site where the stent 16 is implanted. Other means to heat the stent 16 are available, such as using a thermal balloon device, using radio frequency waves to develop heat, or by using induction heating. Such heating methods are well known in the art. The increase in temperature causes the teeth to move from a closed position to an open position and thereby to engage with the edges 54 of the longitudinal slot 48. Once the teeth are engaged and locked, the balloon is deflated and the catheter system and balloon are withdrawn from the vascular system, leaving the stent firmly implanted and in a fully-open and locked position.

An advantage to the described embodiment is that it permits a more uniform and low-pressure expansion of the stent 16, without concern of the teeth 50 catching on the edges of the longitudinal slot and thereby disrupting the deployment and expansion of the stent. Further, because the teeth 50 are very small and susceptible to damage, the fact that the teeth are closed during the expansion process minimizes the risk of damaging the teeth as they pass through the longitudinal slot.

In the preferred embodiment, the material considered best for the present stent is nitinol (NiTi). The shape-memory characteristics of nitinol metallurgically represents a crystalline transition from the martensitic phase to the austenitic phase. The recovery or transition temperature attendant upon the phase transition can be altered by making minor variations in the composition of the metal and in processing the material. In developing the correct composition, biological temperature compatibility must be determined in order to select the correct transition temperature. In other words, when the stent is heated, it must not be so hot so that it is incompatible with the surrounding body tissue. Other shape-memory materials also may be employed, such as, but not limited to, irradiated memory polymers such as auto-crosslink-

able high density polyethylene (HDPEX). As described above, the stent can be manufactured in several ways, including by a laser or by use of chemical etchants. Whatever process is used, the teeth will be annealed and formed so that they lay flush against the stent body in their closed position. The teeth then will be cooled to room temperature so that the teeth remain against the stent body until heated, after the stent is fully expanded and implanted in the vessel wall.

While the invention has been depicted and described as a single stent having a cylindrical shape, a plurality of such stent strut components can be connected together to accomplish the same objective. As an example, and as is depicted in FIGS. 6 and 7, the plurality of stent strut components 60 are interconnected yet have the same basic features as the stent 16 as described in FIGS. 2-5. The open areas 62 can take any form as shown in FIGS. 6 and 7, and can be similar to the open areas 49 as depicted in FIG. 3. Again, the open areas 62 provide greater flexibility to the stent as it is delivered on the balloon and subsequently is expanded to its enlarged diameter. The open areas 62 also provide for cell growth from the vessel wall into and over open areas so that a smooth cell structure eventually lines the inner wall of the stent to provide a restructured vessel. The open areas 62 also allow side branch flow and vessel wall oxygenation.

Because of its unique construction, stent strut components 60 can expand independently of one another and are flexible so that the stent can be implanted on a curved section of a patient's vasculature. As described above, the first edge 40 is inserted through the longitudinal slot 48 respectively for each of the stent strut components 60 depicted in FIG. 6. Further, the closed teeth 50 are in a closed position and will not engage the edges 54 of the longitudinal slot, so that rolling and expansion can take place uniformly and without fear of damaging the teeth. Further, and as has been described above, after stent strut components 60 are expanded to an enlarged configuration, the teeth are moved to an open position as depicted by the open teeth 52 in FIG. 7. The open teeth 52 will engage edges 54 of longitudinal slot 48 thereby locking the stent strut components 60 in a fully open and expanded position.

There are generally two methods by which nitinol may be used with the present invention. Firet, a nitinol foil with SME (shape-memory effect) is heat treated at approximately 500°C. The teeth are mechanically deformed into the closed position so that the teeth remain closed until after the stent has been expanded and the temperature of the stent has been raised to a predetermined level. For example, after the stent has been expanded and deployed in the vessel wall, 45°C heat is applied and the teeth will return to an open position and will be locked into engagement with the longitudinal slot as described above. The application of 45°C of heat is compatible with most applications in the human body, but it is not to be limited to this temperature, as higher or lower temperatures are contemplated without departing from the invention.

A second method includes providing a nitinol foil having SE properties (super-elastic properties) wherein the material is non-malleable and is heat treated to approximately 500°C. In this application, the teeth are deformed and set into a very hydrophilic structure such as hydrogel, glucose, acetate, starch, agar, or similar material. Once the stent is deployed and is expanded in the vessel wall, the teeth will move to an open position as the hydrophilic structure is dissolved. Thus, the teeth will move to engage with the longitudinal slot, thereby locking the stent in its fully open and expanded condition at the injured or diseased area.

In another embodiment of the invention, as depicted in FIGS. 8-10, the teeth which engage the longitudinal slot are shown as a separate add-on section to the main stent. Thus, the stent 16 has several alignment holes 60 that correspond to the alignment holes 60 in teeth sections 63. The teeth sections 63 will overlay the stent 16 and are aligned thereon using a pin or other alignment tool inserted through the alignment hole 60. The teeth sections 63 are attached to the stent 60 by any conventional means such as welding, brazing, adhesives, and the like. Either before or after the teeth sections 63 are attached to the stent 16, the entire structure is laminated with a thin polymer coating which allows for local delivery of drugs loaded in the polymer. The teeth sections 63 can be formed from a nitinol or other shape-memory material such as that described above, while the stent 16 can be made from any of the materials referred to above such as stainless steel, tantalum, polymers, nitinol, and the like. In use, the stent 16 is deployed and implanted in the same manner described above for the other embodiments disclosed. Since the teeth 50 are made from nitinol, they will expand upon application of heat and engage the longitudinal slot 48 in the same manner described above for the other embodiments. The thickness of the stent 16 and the teeth sections 63 can vary depending upon the application, however, they should be as thin as possible in order to provide a low profile for transport through the vascular system of the patient, yet be thick enough to maintain structural integrity when the stent is fully expanded.

Any of the aforementioned embodiments can be laminated according to the following process. The stent, comprised of a nitinol foil having either SME or SE properties, is lased or etched into a specific configuration and thereafter heat treated in its flat condition at approximately 500°C. The structure is laminated with a polymer or similar substance at approximately 190°C. Ideally, the polymer laminate is loaded with a therapeutic drug that will allow for localized drug delivery. The resulting structure can be lased again to refine the configuration, such as to cut the teeth or to cut various apertures so that the stent is more compatible with the biological environment in which it is deployed. The laminate coating is then removed from the teeth so that the nitinol metal

is exposed. The teeth then are collapsed and the stent is rolled into a cylindrical configuration onto the balloon portion of a catheter for intraluminal delivery. The manufacturing processes as described herein can vary, including the temperatures employed and the types and combinations of various materials used. The foregoing methods of manufacture are described for example purposes only and are not meant to be limiting of the invention.

The dimensions of the intravascular catheter described herein generally will follow the dimensions of intravascular catheters used in angioplasty procedures in the same arterial location. Typically, the length of a catheter for use in the coronary arteries is about 150 centimeters, the outer diameter of the catheter shaft is about 0.89 millimeters (0.035 inch), the length of the balloon is typically about 2 centimeters, and the inflated diameter is approximately 1 to about 8 millimeters.

The materials of construction may be selected from those used in conventional balloon angioplasty catheters. The delivery sheath generally will be slightly shorter than the intravascular catheter, e.g., by about the length of the manipulating device 15, with an inner diameter large enough to accommodate the intravascular catheter and to allow the catheter free longitudinal movement therein. The sheath and the catheter shaft can be made of conventional polyethylene tubing, or any other suitable material.

Claims

1. A locking mechanism for an intraluminal stent which is implanted in a body lumen, comprising:

   an intraluminal stent formed from a substantially flat sheet and having a first edge and a second edge;
   a longitudinal slot formed in said first edge;
   a plurality of teeth positioned along a third edge and a fourth edge of said stent for interlocking engagement with said longitudinal slot, said plurality of teeth made from a shape memory-retaining material or a superelastic material; and
   means for locking said plurality of teeth into engagement with said longitudinal slot so that said stent can be rolled into a cylindrical configuration and when expanded to an enlarged diameter said plurality of teeth interlock with said longitudinal slot.

2. The locking mechanism of claim 1, wherein said plurality of teeth move in response to a change in temperature so that said teeth engage with said longitudinal slot thereby locking said stent in an expanded cylindrical form.

3. The locking mechanism of claim 2, wherein said temperature change is accomplished by providing a heated fluid to said stent, thereby moving said plurality of teeth into locking engagement with said longitudinal slot.

4. The locking mechanism of claim 2, wherein said temperature change is accomplished by a catheter having a thermal balloon portion to heat the stent and thereby cause said plurality of teeth to move into engagement and interlock with said longitudinal slot.

5. The locking mechanism for the intraluminal stent of claim 2, wherein said temperature change is accomplished by applying infrared heating to said stent, causing said plurality of teeth to move into locking engagement.

6. The locking mechanism for the intraluminal stent of claim 2, wherein said temperature change is accomplished by applying induction heating to said stent, causing said plurality of teeth to move into locking engagement.

7. The locking mechanism for the intraluminal stent of claim 2, wherein said temperature change is accomplished by a catheter having resister elements providing heat to said stent, thereby causing said plurality of teeth to move into locking engagement with said longitudinal slot.

8. The locking mechanism for the intraluminal stent of claim 2, wherein said temperature change is accomplished by using a catheter to inject a heated fluid into the patient's body lumen adjacent said stent, thereby heating said stent and causing said plurality of teeth to move into locking engagement with said longitudinal slot.

9. The locking mechanism for the intraluminal stent of claim 1, wherein said plurality of teeth are formed from a nickel-titanium alloy.

10. The locking mechanism for the intraluminal stent of claim 8, wherein said intraluminal stent is formed from a material taken from the group of materials including nickel-titanium alloy, tantalum, polymers, and stainless steel, or any composite of said group of materials.

11. The locking mechanism for the intraluminal stent of claim 1, wherein said intraluminal stent is mounted on a balloon portion of a catheter and delivered intraluminally to a diseased area so that said balloon portion can expand and thereby expand said stent at the diseased area.

12. The locking mechanism for the intraluminal stent of claim 1, wherein at least a portion of said stent is encapsulated by a polymeric coating.

13. The locking mechanism for the intraluminal stent of claim 12, wherein said polymeric coating is made from a polymeric composition taken from the group of materials poly-L-lactic acid (LPLA), poly-DL-lactic acid (DLPLA), or polycaprolactone (PCL).

14. The locking mechanism for the intraluminal stent of claim 13, wherein said polymeric coating is loaded with a therapeutic drug.

15. A locking mechanism for an intraluminal stent which is implanted in a body lumen, comprising:

an intraluminal stent formed from a plurality of flat sheets interconnected together and each having a first edge and a second edge;
a longitudinal slot formed in said first edge of each of said flat sheets;
a plurality of teeth positioned along a third edge and a fourth edge of each of said flat sheets for interlocking engagement with said longitudinal slot, said plurality of teeth made from shape memory-retaining materially and
means for locking said plurality of teeth into engagement with said longitudinal slots respectively so that said stent can be rolled into a cylindrical configuration and when expanded to an enlarged diameter said plurality of teeth interlock with each of said corresponding longitudinal slots.

16. The locking mechanism of claim 15, wherein said plurality of teeth move in response to a change in temperature so that said teeth engage with said longitudinal slot thereby locking said stent in an expanded cylindrical form.

17. The locking mechanism of claim 15, wherein at least a portion of said intraluminal stent is made from a nickel-titanium alloy.

18. The locking mechanism of claim 15, wherein said means for locking said plurality of teeth into engagement of said longitudinal slots includes heating said plurality of teeth to a temperature sufficient to cause said teeth to move into locking engagement with said longitudinal slots.

19. A locking mechanism for an intraluminal stent which is implanted in a body lumen, comprising:

an intraluminal stent formed from a substantially flat sheet and having a first edge and a second edge;
a longitudinal slot formed in said first edge;
a plurality of teeth positioned along a third edge and fourth edge of said stent for interlocking engagement with said longitudinal slot, said plurality of teeth made from a super elastic material; and
means for locking said plurality of teeth into engagement with said longitudinal slot so that said stent can be rolled into a cylindrical configuration and when expanded to a large diameter said plurality of teeth interlock with said longitudinal slot.

20. The locking mechanism of claim 19, wherein said plurality of teeth are set into a hydrophilic structure which will dissolve after said intraluminal stent has been implanted in a body lumen, thereby allowing said plurality of teeth to move into locking engagement with said longitudinal slot.

21. The locking mechanism of claim 20, wherein said hydrophilic material is taken from the group of materials including hydrogel, glucose, acetate, agar, and starch.

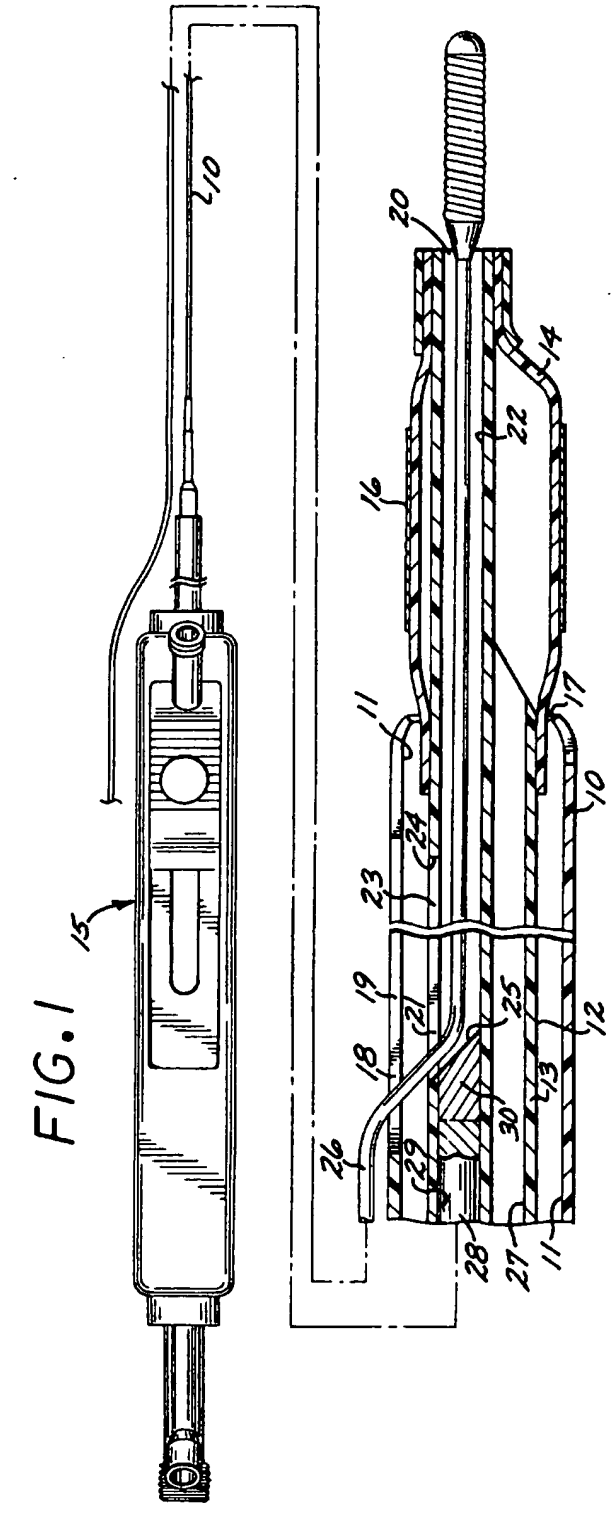
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FIG. 1

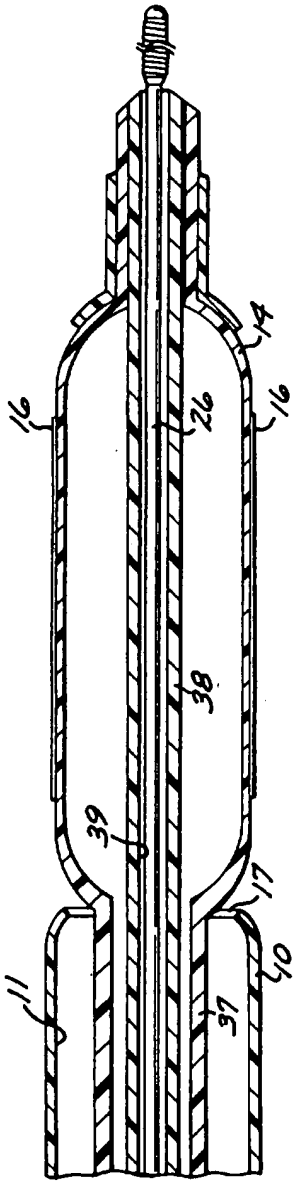
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FIG. 2

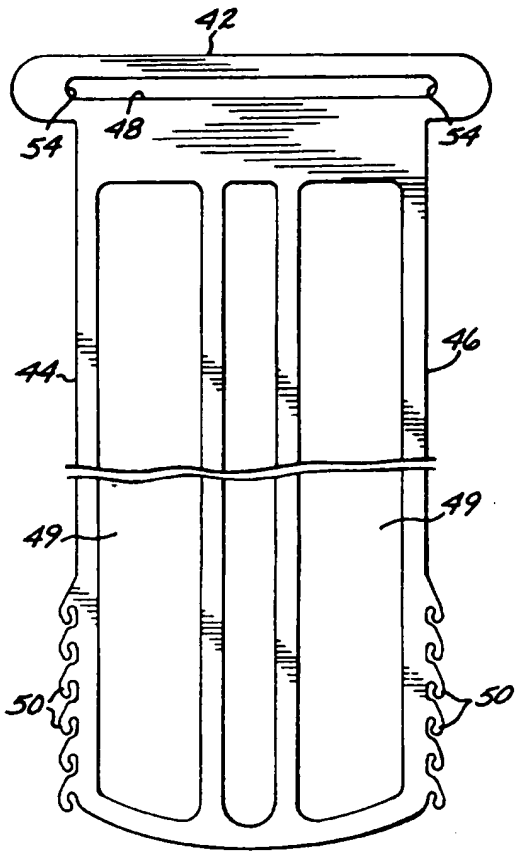

FIG.3

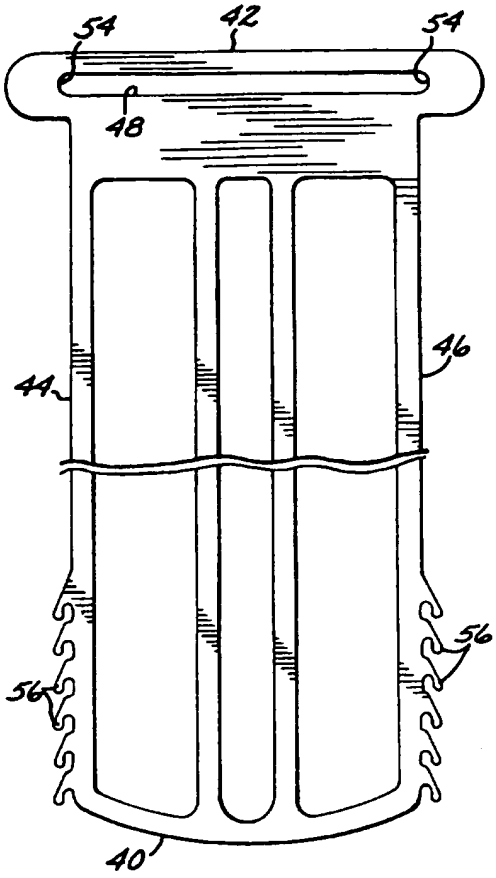

FIG.4

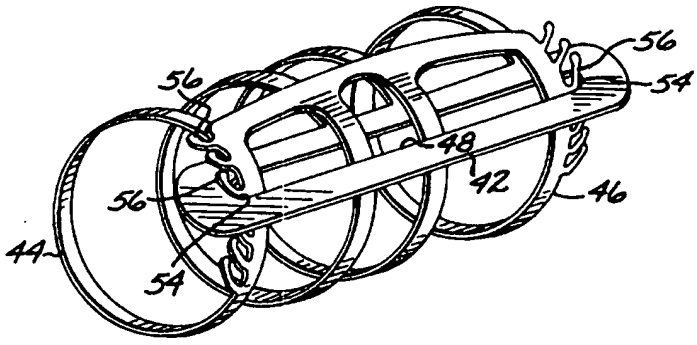

FIG.5

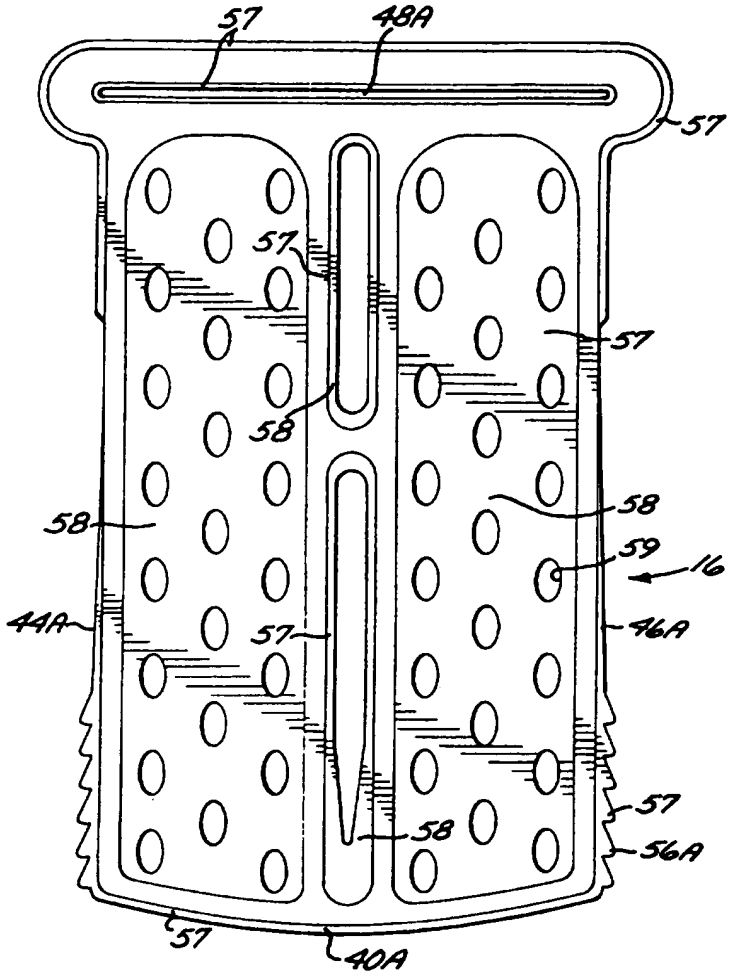

FIG. 4A